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54 **Stroke volume controlled pacer.**

57 A rate responsive pacer which paces the heart at a rate dependent on detected variations in the stroke volume of the heart. A lead system 12 is used for impedance measurements to determine the stroke volume in blocks 20 and 100. The stroke volume is compared at 104 with a reference value which itself may be set at 112 in dependence on the heart rate. A resulting difference value is used in block 106 to determine an appropriate change in heart rate and the heart rate is updated at 108. The heart rate is supplied to pacing circuits 24 via a rate limiting stage 110.

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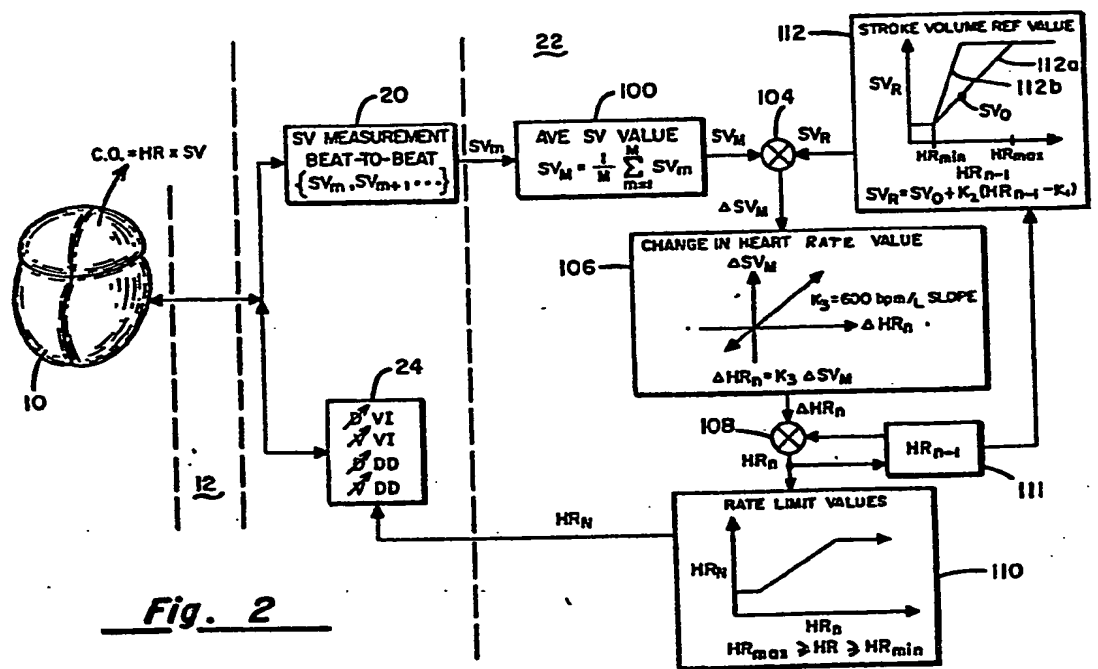


Fig. 2

STROKE VOLUME CONTROLLED PACER

This invention relates generally to the field of cardiac pacemakers, and more particularly, to a pacemaker 5 having an escape interval which is set in response to a measured physiologic variable of the patient.

When the body undergoes exercise, a variety of changes take place. These include an increase in respiration, diversion of blood flow to the active 10 skeletal muscles, and an increase in cardiac output. These changes cooperate to deliver an increased amount of oxygen and nutrients to the active muscles.

The mass flow rate of oxygenated blood from the heart is referred to as the cardiac output of the heart, and it 15 is equal to the product of the heart rate in beats per minute and the heart's stroke volume in litres.

The increase in cardiac output is achieved by an increase in the stroke volume of the heart; up to two fold, as well as an increase in the heart rate; up to three 20 fold.

The changes in stroke volume are mediated by venous return, contractility and afterload, while the changes in the heart's rate are mediated through the autonomic nervous system which operates on a structure called the 25 S-A Node.

The S-A Node is located on the atria of the heart. An electrical signal generated by this natural pacemaker causes the atria, or upper chambers of the heart to contract. This forces blood into the lower chambers or 30 ventricles of the heart. The signal from the S-A Node is propagated to the lower chambers of the heart through a structure called the Atrio-Ventricular or A-V Node after a brief delay. The signal from the A-V Node causes the ventricles to contract, forcing the blood throughout the 35 body.

Many forms of heart disease impair the function of the S-A and A-V Nodes, and their associated conductive tissues. Patients exhibiting these indications may be candidates for artificial pacemaker therapy.

5 Initially, pacemakers were implanted in patients who exhibited complete A-V block. This conduction disturbance is manifested by the inability of the signal from the S-A Node to reach the lower chambers of the heart to initiate a ventricular contraction.

10 The earliest form of implantable pacemaker for the long-term stimulation of the heart is known from U.S. Patent No. 3,057,356 issued to W. Greatbatch. This asynchronous pacemaker, in essence, replaced the heart's natural conduction system and periodically provided an
15 electrical stimulus to the ventricle to cause contractions.

In some patients, the A-V block condition is intermittent and occasionally the artificial pacemaker and the natural S-A Node of the heart compete for control of
20 the ventricular action of the heart. This competition is undesirable. The demand pacemaker avoids this competitive pacing. An example of an implantable version of the demand pacemaker is known from U.S. Patent No. 3,478,746, to W. Greatbatch.

25 In operation, the demand mode pacemaker senses the ventricular contraction of the heart, and provides stimulation to the ventricles only in the absence of a naturally occurring contractions of the heart. Such demand pacemakers synchronize their timing with the heart
30 and provide stimulated beats if the natural cardiac rhythm drops below a preset rate. Both the asynchronous and demand type of pacemaker thus provided for a fixed lower rate for the patient's heart rate.

When a patient has no intrinsic rhythm and is being
35 paced at a fixed rate, any increment in demand for cardiac output must come solely from naturally induced changes in stroke volume. For these patients, strenuous work is

impossible since stroke volume changes alone are insufficient to raise the cardiac output enough to supply the skeletal muscles during heavy exercise.

By way of contrast, the P-synchronous mode of
5 pacemaker, as exemplified by U.S. Patent No. 3,253,596 to J. W. Keller, monitored electrical activity in the atrium, and triggered a ventricular action after a short time period. This form of pacemaker permits the patient's naturally occurring atrial rate to control the rate of
10 ventricular stimulation.

Other pacemakers which exhibit the atrial tracking feature include the atrial-synchronized, ventricularly inhibited pacemaker known from U.S. Patent No. 3,648,707 to W. Greatbatch, as well as the dual-sense, dual-pace
15 pacemaker known from U.S. Patent No. 4,312,355 to H. Funke. The advantage of atrial synchronized pacing is that it permits the pacemaker's rate to be determined by the S-A Node which in turn interprets the body's demand for cardiac output.

20 Another form of rate adaptive pacer is known from U.S. Patent No. 4,298,007 to Wright et al. This device monitors the atrial rate and alters the ventricular escape interval in response to the atrial rate.

For these patients, the pacemaker mimics the natural
25 conductive system of the heart and increased demand for cardiac output comes from both an increase in heart rate controlled by the S-A Node as well as concomitant increase in stroke volume.

However, in many patients, the S-A Node is not a
30 reliable source of information concerning the body's demand for cardiac output. Incorporating an S-A Node replacement to provide rate adaptive pacing would be desirable.

One form of rate responsive pacemaker which relies on
35 the detection of blood saturation of oxygen is known from U.S. Patent No. 4,202,339 to Wirtzfield. This device utilizes an optical measuring probe which is inserted into

the heart to monitor the oxygen saturation of the blood. This measurement is then used to alter the stimulating frequency of an associated pacemaker.

Another form of rate responsive pacemaker is known 5 from U.S. Patent No. 4,009,721 to Alcidi. This device utilizes a pH measurement probe which alters the pacemaker's rate in response to the measurement of blood pH.

Another form of rate adaptive pacemaker is known from 10 U.S. Patent No. 4,140,132 to Dahl, which utilizes an accelerometer to monitor the physical activity of the patient, and which alters the pacemaker's escape interval.

Another form of rate adaptive pacer is known from 15 U.S. Patent No. 4,228,803 to Rickards. This patent discloses a pacer which monitors the Q-T interval of the cardiac cycle and increases the pacer rate in response to shortening of the Q-T interval.

Each of the preceding pacemakers has taken advantage 20 of a physiologic parameter which varies with the body's demand for cardiac output.

Thus, the prior art discloses rate adaptive pacers which monitor a physiologic parameter.

According to the invention, there is provided a 25 cardiac pacer for the therapeutic stimulation of a heart comprising:

measuring means for periodically inferring the stroke volume of said heart and for producing a sequence of stroke volume measurements;

30 a pulse generator for providing stimulation pulses to said heart at a frequency proportional to a heart rate value; and

means coupled to said measuring means and coupled to said pulse generator for determining a heart rate value in 35 response to stroke volume measurement.

In contrast to the preceding forms of rate variable pacemakers, the pacemaker of the present invention monitors

the stroke volume of the patient and alters the pacing rate in dependence thereon. The preferred system controls the patient's heart rate and also permits the stroke volume of the patient's heart to vary over a controlled range.

An embodiment of the invention will now be described by way of example and with reference to the accompanying drawings, in which;

FIG. 1 is a block diagram of a pacemaker incorporating the invention.

FIG. 2 is a flow chart and a functional block representation of the procedure operated by the pacemaker of Fig.1.

FIG. 3 is sequence of graphs which illustrate the relationship between the stroke volume and rate of the heart and cardiac output.

Referring to Fig.3A, it may be seen that the cardiac output of the heart, measured in litres of blood per minute, is the product of the patient's heart rate times the stroke volume of the heart. The figure shows a family of constant cardiac output curves called isopleths corresponding to cardiac outputs of 1 to 6 L/M. As previously indicated, increased physical activity in normal individuals results in an increased cardiac output. In the normal heart, both the heart rate and the stroke volume increase to satisfy the body's need for oxygenated blood. Studies by Versteeg (1981) show that for exercise this cardiac transfer function is a first order linear function with a 10-12 second time constant. This normal cardiac response to increasing work loads is shown by the cardiac load line 300 on FIG. 3A. In the figure, a work load corresponding to cardiac output of 2L/M is met by a heart rate of 75 bpm at a stroke volume of 26 ml. An increase in work load calling for a cardiac output of 5L/M is met with a rate increase to 140 bpm and a stroke volume increase to 36 ml.

In those patients who have complete heart block and a fixed-rate pacemaker, it has been noted that increased demand for cardiac output due to physical exertion results in an increase in the measured stroke volume of a patient's heart. This is depicted in FIG. 3B, where the load line 310 corresponds to pacing at a fixed rate, as in asynchronous (V00), demand pacing (VVI) or A-V sequential (DVI) pacing. This figure indicates that those paced patients who have S-A Node dysfunction can only change stroke volume in response to exercise. For example, at 2 L/M of cardiac output this patient exhibits a stroke volume of 20 ml at a rate of 100 bpm. An increase to 5 L/M calls for a stroke volume increase to 50 ml which may well be beyond the patient's capability.

This response of the heart's stroke volume to physical exertion is well-known in the art.

The present apparatus combines three pacer subsystems with the heart to form a closed loop pacer for pacing the heart.

In FIG. 1, the heart 10 is coupled to a stroke volume measurement apparatus 20 through a lead system 12. The stroke volume measurement system 20 delivers information regarding the stroke volume of the heart to computation and control logic 22. This apparatus utilizes information related to stroke volume to determine a desired pacing rate for the heart. Rate control information is provided to a pulse generator 24 which may provide stimulation to the heart 10 through lead system 12. The pulse generator 24 may operate in any of the known stimulation modes. However, the operation is described in the context of a rate variable asynchronous or V00 mode pacer. A system suitable for incorporating the output data into a demand mode pacer may be found in DE-A-3243094.

STROKE VOLUME MEASUREMENT SYSTEM

In response to an increase in demand for cardiac output the normal heart increases both its rate and stroke volume. The present invention utilizes the body's demand for cardiac output to control the rate of pacing. This technique requires a reliable measurement of a physiologic variable which is related to cardiac stroke volume.

Stroke volume may be inferred by a variety of measurements, taken in the right or left heart including pressure-time histories of arterial blood flow, as well as direct flow measurements in the major blood vessels of the heart.

Another method of determining the stroke volume of the heart is through the technique of impedance plethysmography. This technique has been widely studied (Rushmer 1953, Geddes 1966, Baan 1981). In this technique an electrode system is inserted into the right or left heart. As shown in FIG. 1 current is passed from an anode 13 to a cathode 14 and the voltage between the electrode pair is measured. The accuracy of this method may be increased by utilizing a multiplicity of electrode pairs. (Baan 1981). The magnitude of the voltage measurements from the sensing electrode pairs is a function of the impedance of the heart cavity, (Z_m). This impedance is, in turn, a function of the volume of the chamber. In general, volume resistivity of the blood remains constant, and the magnitude of the voltage sensed depends solely upon the volume of the chamber during the measurement.

One may measure chamber volume sequentially (Z_1 , Z_2 , . . . Z_m) over the entire cardiac cycle and ascertain the maxima and minima of cardiac chamber volume. However, in general, the maximum cardiac volume is achieved at end diastole just prior to the contraction of the ventricle. Likewise, the minimum volume of the ventricle occurs at the end of the contraction of the ventricular muscles called end systole. By measuring the heart volume at end systole and end diastole the stroke volume measurement apparatus may determine the stroke volume for that cardiac contraction or cycle. The computation and control circuitry which receives the stroke volume measurement information may average the stroke volume measurements over a number of cardiac cycles or may operate on a beat-to-beat basis. Further details regarding the measurement of stroke volume through

the use of an intracardiac catheter may be found in Cardiovascular Research, 1981, 15, 328-334.

COMPUTATION AND CONTROL APPARATUS

The structural and functional aspects of computation 5 and control system 22 are shown in FIG. 2.

The computation and control system 22 receives stroke volume information labeled SV_m on a beat-to-beat basis from the stroke volume measurement system 20 which, in turn, is coupled to heart 10. The computation and control 10 system 22 operates on this information and generates a heart rate value labeled HR_M . This rate information is used to control the escape interval of the pulse generator 24 portion of the pacer.

The series of sequential stroke volume measurements, 15 denoted $[SV_m, SV_{m+1}, SV_{m+2} \dots]$ are delivered to a computational block 100 which calculates an average stroke volume value, denoted SV_M , by adding together the values of M measurements and then dividing by M . This process may be expressed:

$$20 \quad SV_M = 1/M \sum_{m=1}^M SV_m$$

Experiments have been performed on dogs where the value of M has been varied from 1 to 12. The control 25 algorithm appears to be relatively insensitive to this interval and a value of $M=1$ may be taken as a representative value.

The measured value of average stroke volume SV_M is compared with a reference value for stroke volume denoted 30 SV_R . The value for SV_R is calculated by functional block 112 which will be described shortly.

The comparison between SV_M and the stroke volume set point SV_R is accomplished by functional node 104 which calculates the difference between the two values 35 yielding a difference value denoted ΔSV_M .

The value of ΔSV_M is used to calculate a value of the change in heart rate value denoted ΔHR_n in the figure. This computation is performed in functional block 106. Experimental work has been performed with a linear relationship between ΔSV_M and the computed value of ΔHR_n expressed:

$$\Delta HR_n = K_3 \Delta SV_M$$

However other relationships satisfying the general expression $\Delta HR_n = f(\Delta SV_M)$ may prove workable.

The proportionality constant K_3 has units of beats per minute/liter. The value of K_3 affects the response time of the system to changes in the measured stroke volume. It appears from animal experimentation that the value of K_3 is not critical for the stability of the system. A typical value for K_3 may be taken as 600 bpm/L.

The value of ΔHR_n computed as a function of ΔSV_M is used to update the existing value for heart rate denoted HR_{n-1} . This calculation is performed at node 108 where the value of change in heart rate (ΔHR_n) is added to the preceding value of heart rate (HR_{n-1}). It is important that this operation preserves the sign of the change of heart rate, so that the updated value of heart rate can increase or decrease in comparison with the preceding value.

The updated value for heart rate (HR_n) is permitted to range between a minimum heart rate value (HR_{min}) and a maximum heart rate value (HR_{max}). The rate limit check is performed by functional block 110. The value of the heart rate delivered to the pulse generator 24 is denoted HR_N where $HR_N = f(HR_n)$. The computed value for HR_N replaces the pre-existing value for HR_{n-1} stored at 111, for use at node 108. This value is used to calculate a new value for the stroke volume reference value SV_R at functional block 112 as follows.

The stroke volume reference value SV_R is set to an initial value SV_0 during system initialization, (normal

-10-

resting value). Subsequent values are computed as a function of the heart rate value,

$SV_R = SV_0 + K_2(HR_{n-1} - K_1)$ where the reference value is a linear function of the existing value of heart rate.

5 However, other relationships satisfying the general expression: $SV_R = f(HR_N - 1)$ may prove workable.

The value of SV_0 sets the operating point of the control system as will be discussed with reference to FIGs. 3c and 3d. The value of the proportionality
10 constant K_2 controls the slope of the cardiac load line discussed in connection with FIGs. 3c and 3d, and the constant K_1 is the heart rate at the set point SV_0 .

The values for the averaging interval M , the initial stroke volume set point SV_0 and K_1 , K_2 and K_3 are likely
15 to be patient specific parameters and it may prove desirable to permit alteration of these values by the physician to adapt the pacer to the patient. Likewise, the values of HR_{max} and HR_{min} may be physician alterable to adapt the stimulation rate to the needs of the
20 patient.

Pulse Generator System 24

The HR_N signal is accepted by the pulse generator system 24 and interpreted as a pacing rate or escape interval for the pacemaker function of the device. In operation, in a demand or VVI
25 pacer, the pacemaker escape interval will vary with the measured stroke volume of the heart. As previously indicated, during exercise the escape interval of the pacemaker will shorten. If the heart fails to beat within the designated escape interval, then a pacing stimulus will be provided,
30 from pulse amplifier 27, to the heart through sensing and stimulating electrode 11 as shown in FIG. 1. If a natural heartbeat is detected prior to the expiration of the escape interval through sensing/stimulating electrode 11, a sense amplifier 26 will inhibit the delivery of the
35 pacing stimulus. Either or both chambers of the heart may be stimulated by the pulse generator.

It should be recognized, however, that the stroke volume controlled system can be incorporated into an atrial tracking pacemaker modality wherein the ultimate escape interval of the pacemaker may be influenced by the detected atrial rate of the heart as well as by variations in the patient's cardiac stroke volume.

Operation

The objective of this stroke volume controlled pacer is to achieve a pacemaker escape interval which reflects the patient's physiologic demand for cardiac output.

The input signal to this control system is the stroke volume of the patient's heart and the output variable of this system is the pacemaker's escape interval.

Experimental data has been taken with a blood flow meter attached to the aorta of the heart, thus providing a direct measure of the stroke volume of the heart, on a beat by beat basis. It is expected, however, that for a fully implantable system it will be preferable to use the impedance plethysmography approach previously described. The integral of the mass flow rate signal from the transducer provides a sequence of stroke volume measurements SV_m . These values may be averaged over a multiple number of cardiac cycles to provide a measure of the average stroke volume of the heart. If a very small number of cycles is used, it is possible that the beat-to-beat variation in the patient's stroke volume may cause the control system to generate a sequence of escape intervals which dither about a physiologically optimum escape rate. On the other hand, if the number of beats taken to form the average is large, the response time of the control system may be insufficient to provide the requisite cardiac output for the instantaneous work level of the patient. Experimental work indicates that a value of $M = 1$ is suitable for a canine with induced heart block.

The average stroke volume value SV_M is compared with a stroke volume reference value which may be selected

by the physician and which is constrained within limits. If this stroke volume reference value is fixed at a specific stroke volume value, then the cardiac load line 320 as shown in FIG. 3C, will have an infinite slope.

5 Under this regime, small increments in stroke volume due to increments in the exercise level of the object result in relatively large increments in heart rate, thus forcing the stroke volume of the heart back toward the set point reference SV_R . In this operating mode the patient is
10 paced at a rate which results in a fixed stroke volume for the heart. Experimental research with canine reveals a potential defect of fixed stroke volume pacing. As indicated in FIG. 3C, an escape interval dictated by fixed stroke volume may call for heart rates substantially above
15 those which are safe for the subject.

By permitting the stroke volume reference point value to vary within constrained limits, one can control the slope of the cardiac load line. Permitting the stroke volume reference point value to vary over a range of
20 approximately 30 ml results in a control system response depicted by FIG. 3D.

In this system the instantaneous value of the stroke volume reference point SV_R is a function of the instantaneous value of the heart rate. The linear
25 relationship depicted by line 112a in functional block 112 of FIG. 2 results in a cardiac load line 330 as shown in FIG. 3D. While a larger value of the proportionality constant K_2 as shown by curve 112b in FIG. 2 results in a cardiac load line similar to cardiac load line 340 in FIG. 3D. Thus,
30 the proportionality constant K_2 controls the slope of the cardiac load line and may vary the cardiac response from that observed in fixed rate pacing as depicted in FIG. 3B to that which results from pacing to a fixed stroke volume depicted in FIG. 3C. An appropriate value for K_2 must be
35 selected by the physician based upon information

concerning the subject patient's heart contractility and stroke volume variations.

The initial value of the stroke volume set point is taken as SV_0 which may also be a physician programmable variable in the pacemaking system. This value controls the initial operating point for the system at resting values of cardiac output. The variation in stroke volume measurement computed at node 104 is utilized to calculate the change in heart rate of the pacemaker in node 106. Once again a linear relationship between the change in heart rate and the change in stroke volume is illustrated in block 106. It is quite likely that other functions may be suitable for these relationships. The value of the proportionality constant K_3 which controls the slope of the function controls the response time of the pacing system to changes in stroke volume of the patient.

Since it is desirable to have a fast acting system it is desirable to have a large value of K_3 . In canine work values for the proportionality constant have varied from 156 bpm/L to 1250 bpm/L with a value of 600 bpm/L proving suitable for canines with induced heart block.

The calculated value of the change in the desired heart rate computed in functional block 106 is added to the existing value of the heart rate and if this new value falls within the limits prescribed by functional block 110 it is delivered to the pulse generator to control the pacing of the patient's heart. It is desirable to have the maximum and minimum heart rates for the system physician prescribed.

CLAIMS

1. A cardiac pacer for the therapeutic stimulation of a heart comprising:

a lead system for coupling said pacer to the patient's heart;

a measuring means coupled to said lead for inferring the stroke volume of said heart from the measurement of a physiologic parameter and for producing a measurement signal indicative of stroke volume;

computation and control means coupled to said measuring means for determining a heart rate value in response to said stroke volume measurement signal; and

a pulse generator means coupled to said lead system and said computation and control means for providing stimulation pulses to said heart at a frequency which is a function of said heart rate value.

2. A cardiac pacer for the therapeutic stimulation of a heart comprising:

measuring means for periodically inferring the stroke volume of said heart and for producing a sequence of stroke volume measurements;

a pulse generator for providing stimulation pulses to said heart at a frequency proportional to a heart rate value; and

means coupled to said measuring means and coupled to said pulse generator for determining a heart rate value in response to stroke volume measurement.

3. A cardiac pacer as claimed in claim 1 or 2 wherein said measuring means is arranged to measure the ventricular volume of said heart at end diastole and at end systole and determine a stroke volume measurement from said end systolic and end diastolic measurements.

4. A cardiac pacer as claimed in claim 1, 2 or 3 wherein said means for determining a heart rate value comprise:

means for comparing the value of said stroke volume measurement with the value of a stroke volume set point for producing a stroke volume difference value;

means for determining a heart rate difference value from said stroke volume difference value; and

means for adding said heart rate difference value to the previous heart rate value yielding a current heart rate value.

5. A cardiac pacer as claimed in claim 4 further including means for determining said stroke volume set point value from said heart rate value.

6. A cardiac pacer as claimed in claim 5 including means for altering the relation between the set point and heart rate values.

7. A method of controlling the escape rate of a pacer comprising the steps of:

a) measuring the cardiac stroke volume;

b) comparing the measured stroke volume with a stroke volume set point value yielding a stroke volume variation value;

c) calculating a heart rate variation value from said stroke volume variation value;

d) adding said heart rate variation value to an existing value of heart rate yielding a heart rate summation value;

e) calculating an updated heart rate value from said heart rate summation value; and

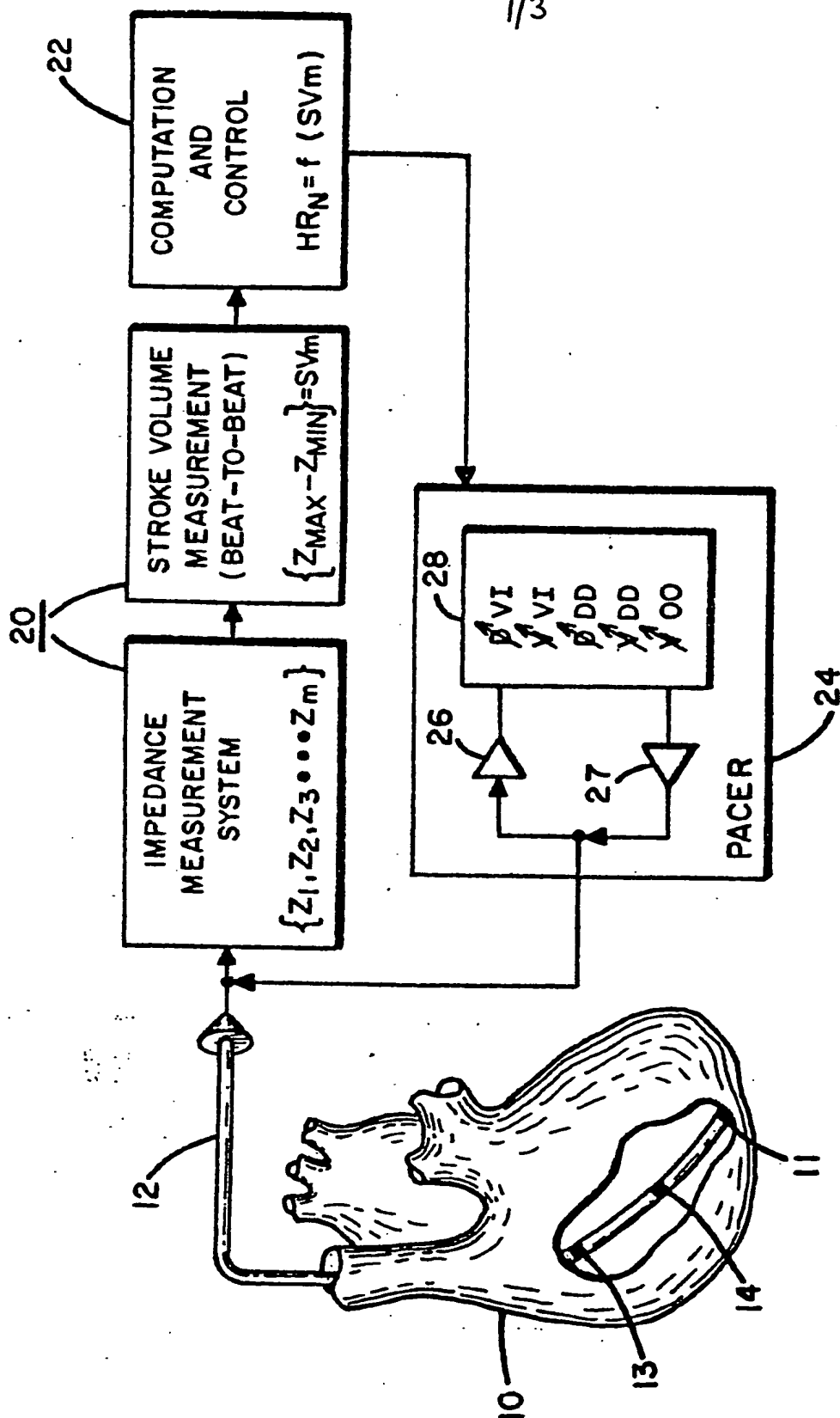
f) setting said escape rate in response to said updated heart rate value.

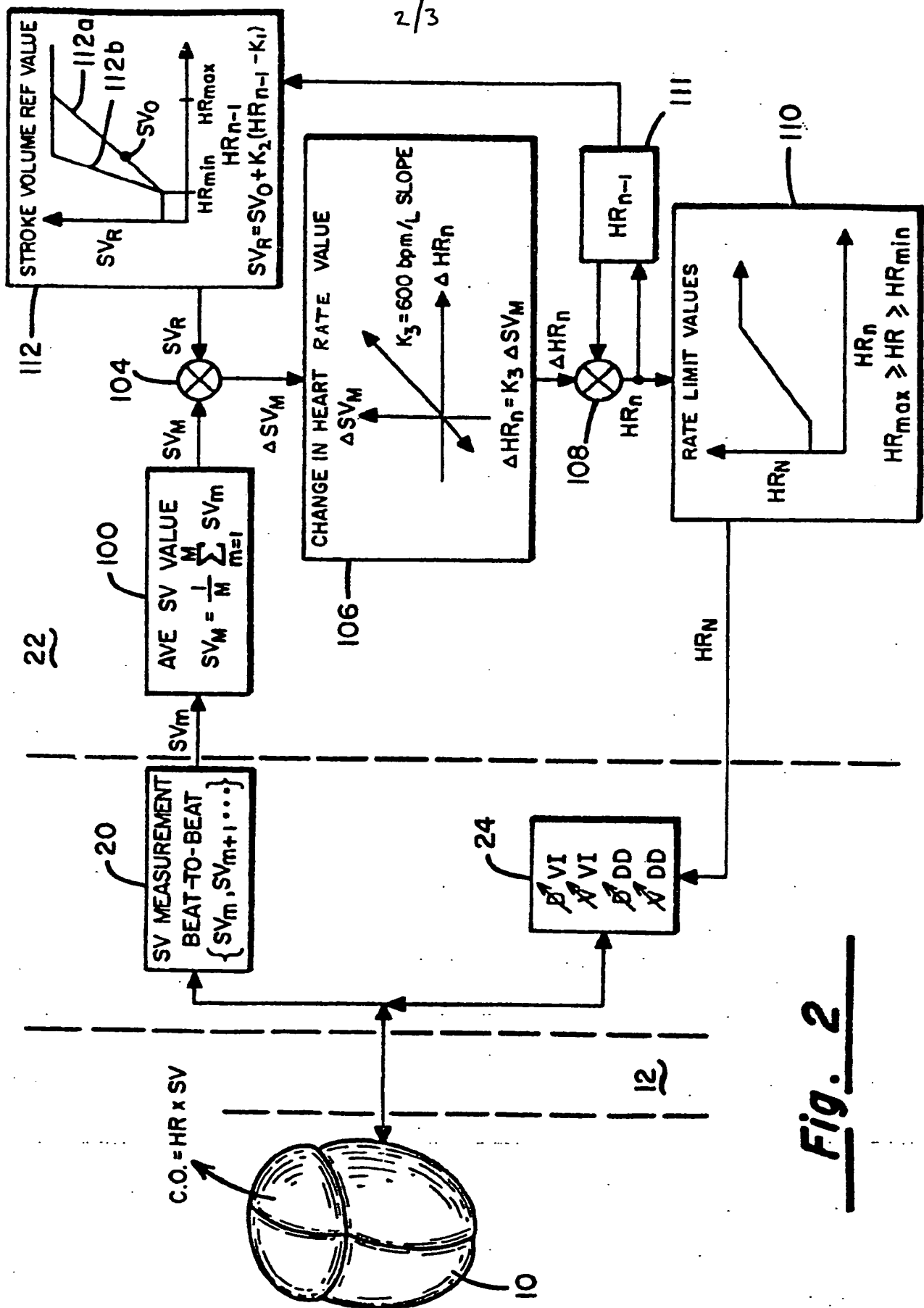
8. A method as claimed in claim 7 wherein said stroke volume set point value is calculated from the existing heart rate value.

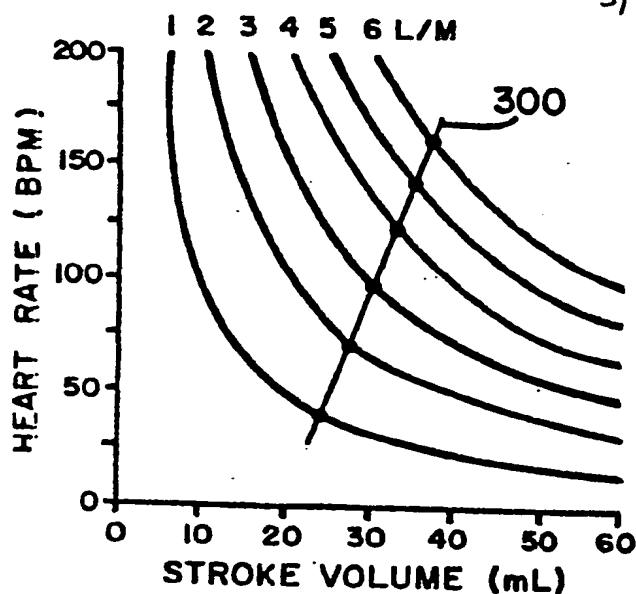
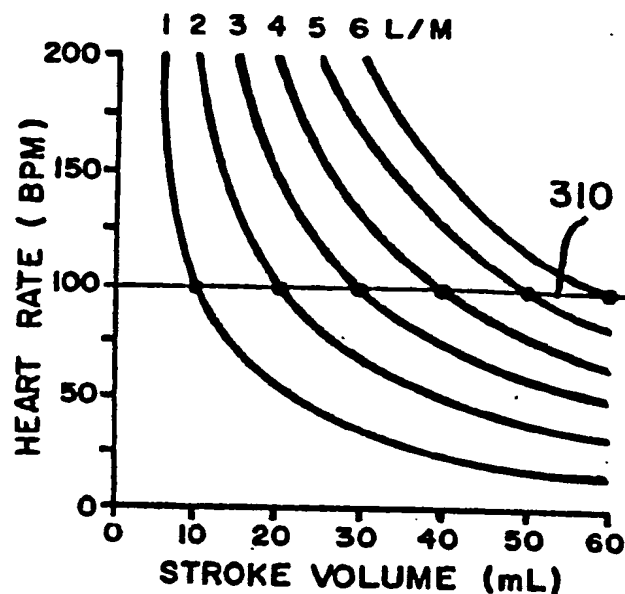
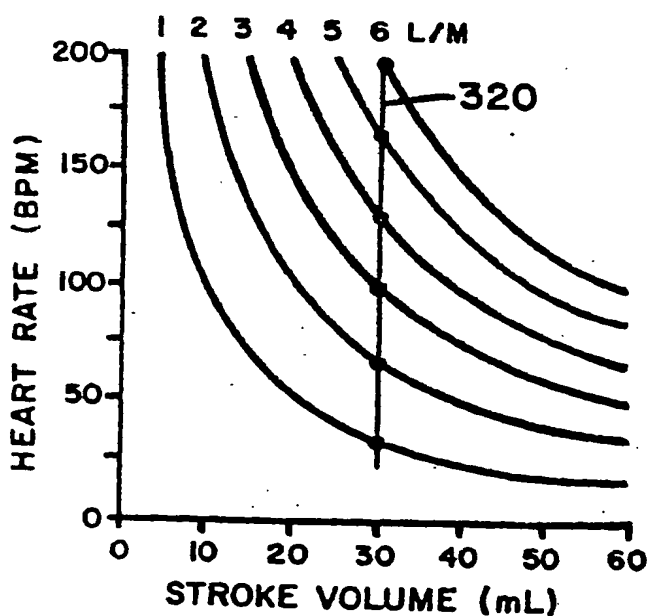
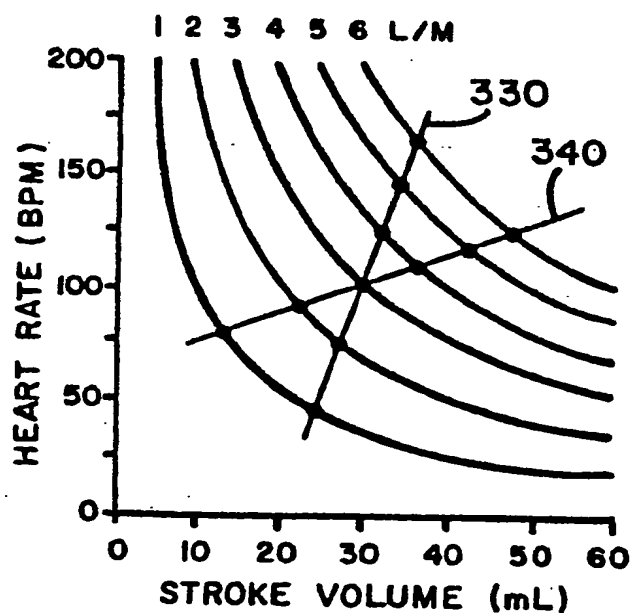
9. A method as claimed in claim 7 or 8 wherein step (a) includes determining the average of a plurality of stroke volume measurements.

10. A method as claimed in claim 7, 8 or 9 wherein step (e) includes limiting the updated heart rate value to within predetermined upper and lower limits.

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Fig. 1

Fig. 2

**A. NORMAL HEART****B. PACED HEART****C. PACING WITH
FIXED STROKE
VOLUME SET POINT****D. PACING WITH
FLOATING STROKE
VOLUME SET POINT**



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EUROPEAN SEARCH REPORT

0140472

EP 84304486.8

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 7)
X	<p><u>DE - A1 - 3 104 938 (MIROWSKI)</u></p> <p>* Abstract; page 12, paragraph 1; page 14, last paragraph - page 15, paragraph 1; page 16, last paragraph - page 17, last paragraph; fig. 1 *</p> <p>--</p>	1-10	<p>A 61 N 1/36</p> <p>A 61 B 5/05</p>
D,Y	<p><u>DE - A1 - 3 243 094 (MEDTRONIC)</u></p> <p>* Abstract; claim 1; fig. 1,2 *</p> <p>--</p>	1,2,7	
D,Y	<p>CARDIOVASCULAR RESEARCH, 15, 1981</p> <p>J. BAAN et al. "Continuous stroke volume and cardiac output from intra-ventricular dimensions obtained with impedance catheter" pages 328-334</p> <p>* Summary; fig. 1 *</p> <p>----</p>	1,2,7	<p>TECHNICAL FIELDS SEARCHED (Int. Cl. 7)</p> <p>A 61 N</p> <p>A 61 B</p>
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 19-09-1984	Examiner NEGWER
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